Remarks
Samuel M. Taylor, President, NCBIO
Senate Judiciary I Pharmaceutical Liability Subcommittee
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Good morning Mr. Chairman, members of the Subcommittee. My name is Sam Taylor; I am president of the North Carolina Biosciences Organization (NCBIO), the trade association for North Carolina's life science industry. NCBIO represents approximately 160 member companies, institutions, and individuals across North Carolina. Our members work in fields ranging from drug discovery, commercialization and manufacturing to agricultural biotechnology.

My colleague, Marjorie Powell, from the Pharmaceutical Research and Manufacturers of America, has already reviewed with you the general principles and benefits of the proposed regulatory compliance defense now under consideration by the subcommittee. The purpose of my remarks today is to provide you with more information about the potential economic impact of the regulatory compliance defense here in North Carolina.

As most of you know, North Carolina is widely considered one of America's leading life science states. A 2010 study prepared for the North Carolina Biotechnology Center[i] shows that North Carolina's life science sector has a statewide economic impact of $64.5 billion annually, directly employs nearly 54,000 North Carolinians, and supports the employment of more than 226,000 people in our State.[ii] That translates into direct and indirect wages of $12.7 billion annually, and more than $1.9 billion a year in state and local tax revenues.

Moreover, the life science sector is one of the fastest growing parts of North Carolina's economy. The Biotechnology Center's 2010 economic impact study also showed that employment in North Carolina's life sciences sector grew by almost 30% between 2001 and 2008. That growth rate was nearly twice that of the United States' life science sector nationally during the same period, and more than five times the rate of North Carolina's private sector employment growth.[iii]

Finally, it's important to note that our State's life science sector reaches to nearly every geographic area of North Carolina. Baxter Laboratories, for example, operates the world's largest intravenous solutions manufacturing facilities in Marion, North Carolina. Greer Laboratories is in Lenoir, Actavis in Lincolnton, Targacept in Winston-Salem, Chelsea Therapeutics in Charlotte, Pfizer in Sanford, Novartis in Holly Springs, Grifols in Clayton, Merck in Wilson, DSM in Greenville, West Pharmaceutical Services in Kinston. Wilmington is home to PPD, one of the largest clinical research organizations in the world. And, of course, the Research Triangle area is home to a host of life science companies large and small, including Merck, Biogen Idec, Eaisi, and GlaxoSmithKline.[iv]

Of course, the growth of North Carolina's life science sector is no accident. North Carolina has been systematically investing in its life science economy for more than twenty years. We are home to the

first, and still one of the only, publicly supported biotechnology centers in the world. We have also invested heavily in life science research and training in our university and community college systems. Just last year, for example, this legislature voted to continue its $50 million annual appropriation to support cancer research at the University of North Carolina. And at Winston-Salem, you have allocated more $8 million annually to the Wake Forest Institute for Regenerative Medicine.

As I have already noted, these investments are paying off for North Carolina economically. But they are also paying off for our citizens and for people around the world in terms of better health care and quality of life. Some examples:

- Novartis has opened America's first cell-based influenza vaccine manufacturing facility at Holly Springs. A collaboration with the federal Department of Health and Human Services, the project radically accelerates the process for bringing vaccines for new strains of flu to patients.[v]
- BioCryst Pharmaceuticals, located in the Research Triangle, has just completed successful preclinical trials on a new drug for Hepatitis C.[vi]
- Chelsea Therapeutics, of Charlotte, has been granted priority review by the FDA for a new drug to help victims of Parkinson's Disease.[vii]
- DARA Biosciences, of Durham, has received FDA priority review for a new pain treatment for cancer patients.[viii]
- Entegrion, of Research Triangle Park, has received $43 million from the Department of Defense for development of a dried blood plasma product that could be administered to wounded soldiers on the battlefield.[ix]
- GlaxoSmithKline has received FDA approval for the world's first Lupus treatment in 56 years[x] and has conducted successful clinical trials for a new malaria vaccine in Africa.[xi]
- Medicago has begun operation of a new manufacturing facility to produce vaccines from tobacco plants in Research Triangle Park.[xii] In addition to its primary work to produce influenza the company recently announced it is targeting rabies.[xiii]
- Nephrogenex, of Research Triangle Park, has received accelerated review of Phase III clinical trials for a new treatment for kidney damage associated with diabetes.

But the momentum of North Carolina's life science community in creating both new jobs and new treatments for disease is subject to a number of negative trends nationally.

Of primary importance, the cost of developing safe and effective new drugs continues to grow. In 2002, The Tufts Center for the Study of Drug Development estimated the capitalized cost of bringing a new drug to market at approximately $800 million.[xiv] In 2010, a similar study pegged these costs at $1.2 billion.[xv] While these estimates have been widely disputed, the point here is not so much the cost – although the process plainly requires large financial resources -- but its *escalation*.

While development costs are rising, new financial burdens are being placed on the life science industry. The Accountable Care Act of 2010, for example, imposes, effective in 2011, a new Branded Prescription Drug Fee designed to collect $2.6 billion annually from the pharmaceutical industry. By 2018, the amount will increase to $4.1 billion per year.[xvi] Drug reimbursement rates are also under pressure. Last year, as Congress grappled with the federal deficit, negotiators repeatedly considered cuts in the average sales price-based reimbursement rate for health care providers who purchase drugs for administration to patients in hospitals and doctors' offices. [xvii] And just a few days ago, President Obama suggested, in his annual budget recommendations to congress, that pharmaceutical companies be required to pay steep rebates to the government on drugs sold under Medicare Part D.[xviii] The proposed changes would cost pharmaceutical manufacturers $156 billion over ten years.[xix]

Finally, like all American companies, life science businesses are being exposed to increasing costs of litigation to address claims of civil liability. Annual civil liability costs in the United States, on average, are increasing faster than nominal GDP. Even setting aside judgments and settlements, litigation transaction costs are rising substantially. A recent survey of Fortune 200 companies found that the average litigation cost per company (excluding internal company costs) was nearly $115 million in 2008, up 73 percent from $66 million in 2000 – representing an average increase of 9 percent each year.[xx] Between 2000 and 2008, average annual litigation costs as a percent of revenues increased 78 percent for the companies providing this data for the full survey period.[xxi]

All these factors point to one inescapable conclusion – resources for drug development – and the treatments and jobs that it generates – are not only finite, but increasingly inadequate to meet the demands and opportunities created by our health care system. Stated another way – it is becoming increasingly difficult for drug companies large and small to marshal the enormous resources required to create new treatments and new jobs.

The regulatory compliance defense that you are considering today gives the North Carolina General Assembly an opportunity to continue its leadership in supporting the economic and health benefits of the life sciences. As Ms. Powell has indicated, the proposed language begins to appropriately link the liability of drug manufacturers to an appropriate standard of care for drug development activities – that is, the new drug approval requirements of the U.S. Food and Drug Administration.

So how, specifically, will the proposed defense benefit North Carolina?

First, it will free our large pharmaceutical manufacturing companies to spend more money on research, development and manufacturing. Naturally, these funds will be spent across each company's global footprint. But North Carolina, because of its exceptional concentration of drug development and manufacturing operations, will receive substantially greater economic benefits than America on

average. And of course these economic benefits are in addition to improvements in health and quality of life that are made possible by expanded drug discovery and research.

Second, and perhaps less obviously, the regulatory compliance defense will benefit North Carolina's small life science companies as well. Like our large companies, these firms will benefit from reduced cost of litigation and greater certainty around potential civil liability. But our small firms will benefit in a second way as well – through greater access to innovation capital.

All of you who are in business know that financial resources are scarce. But in the world of life science, the scarcity of financial resources is the number one rate-limiting factor to success. New discoveries and technologies absolutely cannot be commercialized without adequate financial resources.

In other life science hubs, such as California and Massachusetts, financial support for innovation comes from a strong network of angel investors and venture capital companies. The size and number of angel and venture capital funds in North Carolina, however, pale in comparison to these other states. In 2008, for example, venture capital investments in California totaled roughly $15 billion dollars.[xxii] For the same year in North Carolina, venture investments totaled less than $500 million.[xxiii]

Because of our relative lack of venture capital, North Carolina must look to others sources to fund our start-up drug development companies. In many cases, these sources include large pharmaceutical companies. Two good examples come immediately to mind.

In Winston-Salem, the drug development Targacept, has become one of our state's leading life science start-up companies by partnering with larger drug development companies. In 2009, the company entered into a key drug development partnership with AstraZeneca to support development of several drugs for depression and other central nervous system disorders. Under the agreement, AstraZeneca will provide as much as $1.24 billion dollars to support Targacept's work on key compounds. Targacept has already received $200 million of this amount.[xxiv] Another agreement between Targacept and GlaxoSmithKline, paid Targacept $45 million.[xxv]

A similar symbiosis is underway in Morrisville, where start-up company Viamet Pharmaceuticals is in a partnership with Novartis that could ultimately pay Viamet as much as $200 million.[xxvi] The partnership was launched in 2010 and is based on Viamet's unique capabilities around unique science licensed from the University of North Carolina at Chapel Hill.

The stories of Targacept and Viamet are not unique. NCBIO estimates based on media reports that North Carolina life science companies have received nearly $450 million in licensing payments from large pharmaceutical companies since 2009.[xxvii] While these payments are not the whole answer to North Carolina's commercialization capital needs, they are a big piece of the equation.

In summary, controlling civil liability-related costs through the proposed regulatory compliance defense is good policy for North Carolina. By appropriately adopting FDA approval benchmarks as a standard of care in drug development, the defense will free capital at a time when it is desperately needed to support the development of new treatments for disease and economic activity that results from this work. Adoption of the defense in North Carolina, because of our leadership role in the life sciences, will facilitate not only improved health care and quality of life for our citizens, but greater economic activity and job creation as well. Furthermore, these benefits will flow not just to large pharmaceutical companies that maintain research and manufacturing operations here, but to the earlier-stage life science companies in North Carolina that look to larger drug companies for financial resources to advance new products.

For these reasons, I urge you to give favorable consideration to the proposed regulatory defense that you are considering today.

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[i] Battelle Memorial Institute, Evidence & Opportunity: Biotechnology Impacts in North Carolina (2010)(hereinafter, "Battelle Report").
[ii] Battelle Report at 33.
[iii] Battelle Report at 8.
[iv] The North Carolina Biotechnology Center maintains a current database of life science companies in North Carolina. The database can be accessed on the Center's website at http://directory.ncbiotech.org/directory.
[v] MedCity News, **N.C. Novartis site is first cell-based flu vaccine facility in the country** (December 12, 2011).
[vi] MedCity News, **Hepatitis C compound from BioCryst set for 4Q IND filing** (February 15, 2012).
[vii] MedCity News, **Chelsea's Northera for Parkinson's patients gets FDA priority review** (November 17, 2011).
[viii] WRAL Techwire, **FDA grants 'fast track' status for DARA BioSciences drug** (August 19, 2011).
[ix] MedCity News, **Entegrion's plasma technology gets $43.7M Defense Department contract** (October 4, 2011).
[x] MedCity News, **FDA approves GSK lupus drug Benlysta** (March 9, 2011).
[xi] MedCity News, **GSK on brink of first malaria vaccine; trial results show risk cut by half** (October 18, 2011).
[xii] WRAL Techwire, **Vaccine developer Medicago receives $3.5M payment** (February 13, 2012).
[xiii] WRAL Techwire, **Vaccine firm with new RTP plant is targeting rabies** (January 20, 2012).
[xiv] DiMasi, Joseph A, *et al.*, The Price of Innovation: New Estimates of Drug Development Costs (October 2002).
[xv] Paul, Steve, et al., "How to Improve R&D Productivity: the Pharmaceutical Industry's Grand Challenge," Nature News Drug Discovery (March 2010).
[xvi] Patient Protection and Affordable Care Act of 2010, §1404.
[xvii] Letter from Congressman Leonard Lance to The Honorable John Boehner, Speaker United States House of Representatives (July 21, 2011).
[xviii] Pharmalot, **Obama Budget & Pharma: Highlights Or Lowlights?** (February 14, 2012).
[xix] Id.
[xx] Lawyers for Civil Justice et al., *Litigation Cost Survey of Major Companies* 7-8 & fig. 4 (2010). This figure reflects responses from 20 companies in 2000 increasing to 36 companies in 2008. The average litigation costs for the 20 companies responding for all years increased from $66 million in 2000 to $140 million in 2008, while the total litigation costs of these 20 companies grew from $1.3 billion in 2000 to $2.75 billion in 2008. *Id.* at 8 & fig. 5.
xxi Id. at 9 & fig. 5 (14 companies responding).
[xxii] See SSTI Venture Capital Dashboard at http://www.ssti.org/vc/index.php.

[xxiii] Id.
[xxiv] BusinessNC.com, A Nicotinic Fit, September 2010.
[xxv] Id.
[xxvi] News Release, Viamet Pharmaceuticals and the Novartis Option Fund Enter Agreement for Development of Novel Metalloenzyme Inhibitors (February 20, 2010).
[xxvii] See NCBIO's listing of North Carolina life science investments, grants and licensing payments at http://ncbioscience.net/bioscience-news/News.aspx.